K112755

MAR 27 2012

510(k) Summary

Submitter	Diatron US Inc. 14026 W. 107th Street Lenexa, Kansas 66215-2005
Contact Person	Michael Switzer, Director, Quality Assurance P: 954-790-9550 F: 954-827-2644 E: mike.switzer@diatron.com
Date Prepared	March 19,2012
Trade Name	Abacus 5, Automated Hematology Analyzer
Classification	Class II Automated Differential Cell Counter 21 CFR §864.5220
Product Code	GKZ
Predicate Device(s)	The subject device is equivalent to the following device: Abbott CELL-DYN® 3700 (K991605)
Device Description	The 'Abacus 5' is a fully automated high quality hematology analyzer for *in vitro* diagnostic use in clinical laboratories. It provides precise and accurate 5-part differential measurement using a laser based optical measurement technology. The 'Abacus 5' analyzer uses the impedance method for measurement of leukocytes (WBC), erythrocytes (RBC) and platelet (PLT) concentrations. Measurement of the hemoglobin (HGB) content of red blood cells is accomplished by photometric measurement technology. Five part leukocyte differential (LYM%, MON%, NEU%, EOS%, BAS%) is accomplished using optical laser-based flow cytometric technology. A vivid color touch screen display is featured with an intuitive, informative, and attractive user interface. A START button allows one-touch operation for ease of use. The 'Abacus 5' analyzer's unique software system supports the use of many commonly used external printers with its USB connections. The 'Abacus 5' internal database is capable of storing 100,000 patient, QC, and calibration result records including flags and graphical scatter diagrams and histograms. The system software is field-upgradeable to ensure up-to-date operation. An automatic optional Autosampler is available (sold separately) for automated processing of up to 100 sample tubes for increased laboratory efficiency. The 'Abacus 5' features advanced Ethernet LIS connectivity using the HL7 protocol in addition to standard serial interfaces, providing the clinical laboratory with flexible connectivity options.
Intended Use	The Diatron Abacus 5 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters in K_3EDTA anti-coagulated venous whole blood samples: WBC, LYM%, LYM#, MON%, MON#, NEU%, NEU#, EOS%, EOS#, BAS%, BAS#, RBC, HGB, HCT, MCV, MCH, MCHC, RDWcv, RDWsd, PLT and MPV. The Diatron Abacus 5 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.
Functional and Safety Testing	To verify that device design met it's functional and performance requirements, a representative sample of the device underwent software and system verification and validation testing, in accordance with Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood cells. A risk and hazard analysis was performed per ISO 14971.

Substantial Equivalence: Similarities

Item	Diatron Abacus 5	Abbott CELL-DYN 3700
Indication for Use Statement	The Diatron Abacus 5 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters in K_3EDTA anti-coagulated venous whole blood samples: WBC, LYM%, LYM#, MON%, MON#, NEU%, NEU#, EOS%, EOS#, BAS%, BAS#, RBC, HGB, HCT, MCV, MCH, MCHC, RDWcv, RDWsd, PLT and MPV. The Diatron Abacus 5 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.	The Diatron Abacus 5 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters in K_3EDTA anti-coagulated venous whole blood samples: WBC, LYM%, LYM#, MON%, MON#, NEU%, NEU#, EOS%, EOS#, BAS%, BAS#, RBC, HGB, HCT, MCV, MCH, MCHC, RDWcv, RDWsd, PLT and MPV. The Diatron Abacus 5 is indicated for use to identify patients with hematologic parameters within and outside

		of established reference ranges.
Sampling Mechanisms	- manual sampling (one sample at a time) - autosampler sampling - cap piercing function for closed tubes - interchangeable sample adapters for different tube types - automatic aspiration of specimen and presentation for automated processing	Same
Sample Processing	Open vial mode, closed vial mode and autosampler	Same
Sample ID	Manual and Barcode	Same
Methodology	WBC = Impedance NEU = Calculated NEU% = Optical LYM = Calculated LYM% = Optical MON = Calculated MON% = Optical EOS = Calculated EOS% = Optical BAS = Calculated BAS% = Optical RBC = Impedance HGB = Photometric HCT = Calculated MCV = Derived MCH = Calculated MCHC = Calculated RDWcv = Derived RDWsd = Calculated PLT = Impedance MPV = Derived	Same
WBC Differential	NEU%, LYM%, MON%, EOS%, BAS%	Same
Sample Type	K_3 EDTA anticoagulated venous whole blood	Same
Parameters	WBC, NEU, NEU%, LYM, LYM%, MON, MON%. EOS, EOS%, BAS, BAS%, RBC, HGB, HCT, MCV, MCH, MCHC, RDWcv, RDWsd, PLT, MPV	Same
QC	Maintains QC files, generates Levey-Jennings Charts	Same
Calibration	Manual calibration and SW supported calibration in automatic mode	Same
Flags/Alerts	Dispersional data alerts, suspect parameter messages and suspect population flags to assist in data review	Same
Barcode Reader	Built-in barcode readers in the autosampler	Same
External Printing	External printing capabilities with a compatible printer	Same
Data Input/Ouput	Accept input from the keyboard and send data output to the video screen, hard drive and printer	Same
Microprocessors	Use microprocessors for systems control, data acquisition and data analysis	Same

Substantial Equivalence: Differences

Item	Diatron Abacus 5	Abbott CELL-DYN 3700
Methodology	Uses the impedance method for WBC; the RDWsd is calculated	Uses simultaneous optical and impedance measurements for WBC; the RDWsd is derived
Parameters	Measures RDWcv; does not measure RETC, %RETC, IRF	Does not measure RDWcv; measures RETC, %RETC, IRF
Throughput	60 samples per hour	90 samples per hour
Sample Aspiration Volume	Open Vial Mode - 110µl Closed Vial Mode - 110 µl Autosampling - 110 µl	Open Vial Mode - 130 µl Closed Vial Mode - 240 µl Autosampling - 355 µl
Reagents	Manufactured specifically for the Abacus 5	Manufactured specifically for the Cell-Dyn 3700; also has a specific RETC reagent system

	Calibrator and Controls	Recommends R&D Systems Calibrator and Controls	Abbott CELL-DYN Calibrator and Controls
	Data Storage	100,000 records including flags, scatter and histograms, QC records	10,000 records including flags, scatter and histograms
	Interface to On-line LIS	Bidirectional RS232 or Ethernet interfacing	Bidirectional RS232 interfacing
	Keyboard	Optional keyboard, connected through PS/2 or USB	Comes with keyboard connected through PS/2
	Barcode Reader	Optional manual barcode reader connected via USB port	Manual barcode entry via keyboard
	Peripheral Ports	1- PS/2 mouse port 1- PS/2 keyboard port 2- COM ports for LIS 1- DVI-D port (unused) 1- VGA port (unused) 2- RJ45 Ethernet port for LIS 4- USB 2.0 ports 3- Audio jacks	1- VGA port 1- Audio port 1- USB port
Performance	All required software and system verification and validation procedures have been executed and analyzed per FDA recommended standards and the Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells. All risk and hazard analysis have been performed and documented per ISO 14971 guidelines. All performance and accuracy summary data and conclusions can be referenced in document # A5-05-0020-02, Validation Report of Abacus 5 Hematology Instrument, Revision 2, that is included with this submission. All performance and accuracy data and data analysis in this submission support and substantiate equivalence to the selected predicate device.(Abbott CELL-DYN 3700, K991605).		
Conclusion	Diatron concludes, based on all information submitted and discussed in this submission and in this summary, that the Diatron, Abacus 5 is substantially equivalent to the tested predicate device and has demonstrated to be a safe and effective product to be marketed in the United States.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Diatron US, Inc.
c/o Mr. Michael Switzer
Director, Quality Assurance
14026 W. 107th Street
Lenexa, KS 66215

MAR 2 7 2012

Re: k112755
Trade/Device Name: Abacus 5
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: February 15, 2012
Received: February 17, 2012

Dear Mr. Switzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

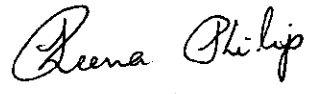
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112755

Device Name: Abacus 5

Indications for Use:

The Diatron Abacus 5 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters in K_3EDTA anti-coagulated venous whole blood samples: WBC, LYM%, LYM#, MON%, MON#, NEU%, NEU#, EOS%, EOS#, BAS%, BAS#, RBC, HGB, HCT, MCV, MCH, MCHC, RDWcv, RDWsd, PLT and MPV. The Diatron Abacus 5 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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